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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/719,415

11/21/2003

Dusan Pavcnik

PA-5360-RFB

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9896 7590 06/22/2007  
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EXAMINER

PRONE, CHRISTOPHER D

ART UNIT

PAPER NUMBER

3738

MAIL DATE

DELIVERY MODE

06/22/2007

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

**Office Action Summary**

Application No.

10/719,415

Applicant(s)

PAVCHNIK ET AL.

Examiner

Christopher D. Prone

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 25 April 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1 and 3-20 is/are pending in the application.
- 4a) Of the above claim(s) 3, 13, 15 and 19 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1, 4-12, 14, 16-18 and 20 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_

## **DETAILED ACTION**

### ***Continued Examination Under 37 CFR 1.114***

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 4/25/07 has been entered.

### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1, 4-12, 14, and 16-20 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter, which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The claims require that the distal and proximal most portions of the first stent are coincident with the distal and proximal most ends of the graft, but this is never recited within the specification. The specification leaves the description in a broad manner simply reciting the distal and proximal ends. The figures elected by the applicant, figure 1 and 2, show the first stent

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as having extensions 66 as its distal and proximal most portions that is clearly not coincident with the graft ends.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1, 6, 9-11, 14, 17, 18, and 20 are rejected under 35 U.S.C. 103(a) as being unpatentable over United States Patent 5,865,723 Love in view of United States Patent 5,571,173 Parodi.

Love discloses the invention substantially as claimed comprising expandable first inner stent 16, expandable second outer stent 14, and a tissue graft layer 12 comprising an extra cellular matrix material collagen disposed on the first stent and under the second. Love also discloses that the stent may comprise a plurality of circumferential segments and a plurality of tie bars shown in figure 9. In regards to claims 17, figure 2 of Love shows that the outside diameter of the first stent is greater than the inside diameter of the second stent. In regards to claim 18 Love further discloses that the first and second stents have equivalent inside and outside diameters (7:25-37).

However, Love does not disclose that the distal and proximal most portions of the first stent are coincident with the distal and proximal most ends of the graft.

It is old and well known in the art of stent grafts to make the stents and graft ends coincident. An example of an old patent teaching coincident proximal and distal graft and stent ends is USPN 5,571,173 Parodi (see figures 22 and 23).

It would have been obvious to one having ordinary skill in the art at the time the invention was made to make the implant of Love have stent and graft ends be coincident as taught by Parodi in order to provide enhanced the implants ability to completely expand and anchor to the vessel.

Claims 4, 5, 7, and 8 are rejected under 35 U.S.C. 103(a) as being unpatentable over Love in view of Parodi and further in view of United States Patent 6,358,284 B1 Fearnot et al.

The combination of Love in view of Parodi discloses the invention substantially as claimed being a stent tissue graft. However, Love does not disclose that the tissue graft comprises multiple layers of submucosa.

Fearnot teaches the use of tubular grafts comprising layers of submucosa sheets in the same field of endeavor for the purpose of providing enhanced repair of damaged or diseased host tissues.

It would have been obvious to one having ordinary skill in the art at the time the invention was made to combine the submucosa tissue graft layers as taught by Fearnot with the stent graft of Love as modified by Parodi in order to provide enhanced repair of damaged or diseased host tissues.

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Claims 1, 12, and 16 are rejected under 35 U.S.C. 103(a) as being unpatentable over United States Patent 5,628,788 Pinchuk in view of United States Patent 5,571,173 Parodi and further in view of United States Patent 6,358,284 B1 Fearnot et al.

Pinchuk discloses the invention substantially as claimed being a double-layered stent graft wherein the inner stent is smaller than the outer stent. However, Pinchuk does not disclose that the graft comprises multiple layers of tissues or that the distal and proximal most portions of the first stent are coincident with the distal and proximal most ends of the graft.

Fearnot teaches the use of tubular grafts comprising layers of submucosa tissue sheets in the same field of endeavor for the purpose of providing enhanced repair of damaged or diseased host tissues.

It is old and well known in the art of stent grafts to make the stents and graft ends coincident. An example of an old patent teaching coincident proximal and distal graft and stent ends is USPN 5,571,173 Parodi (see figures 22 and 23).

It would have been obvious to one having ordinary skill in the art at the time the invention was made to combine the submucosa tissue graft layers as taught by Fearnot and the extended stent lengths allowing them to be coincident with the graft ends as taught by Parodi with the double layered stent graft of Pinchuk in order to provide enhanced repair of diseased host tissues and better anchoring and expansion.

### ***Response to Arguments***

Applicant's arguments with respect to claims 1, 4-12, 16-18, and 20 have been considered but are moot in view of the new ground(s) of rejection.

**Conclusion**

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christopher D. Prone whose telephone number is (571) 272-6085. The examiner can normally be reached on Monday Through Fri 8:30 to 5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine McDermott can be reached on (571) 272-4754. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Christopher D Prone  
Examiner  
Art Unit 3738

CDP

  
EDUARDO C. ROBERT  
SUPERVISORY PATENT EXAMINER